K120435

STERIS®

JUN - 4 2012

510(k) Summary
For
Browne Aldahol Glutaraldehyde Indicator

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Summary Date: February 10, 2012

1. Device Name

Trade Name:	Browne Aldahol Glutaraldehyde Indicator
Common/Usual Name:	Browne Aldahol Test Strip
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ).

2. Predicate Device

- K924681 – 3M™ Comply™ Cold Sterilog™ Glutaraldehyde Monitor 3987MM

3. Description of Device

The Browne Aldahol Glutaraldehyde Indicator is a chemical indicator strip consisting of an absorbent paper pad impregnated with the reactive chemicals, which is adhesively bonded to one end of a polymer film. The Browne Aldahol Glutaraldehyde Indicator has been developed to monitor the active glutaraldehyde concentration of Aldahol V High-Level Disinfectant (K113015) solution that has an MRC of 1.8% glutaraldehyde.

4. Intended Use

The Browne Aldahol Glutaraldehyde Indicator is a glutaraldehyde concentration monitor dedicated for use with Aldahol V High-Level Disinfectant solution cleared under K113015. The purpose of the Browne Aldahol Glutaraldehyde Indicator is to determine whether the glutaraldehyde concentration of an Aldahol V High-Level Disinfectant solution is above the minimum recommended concentration, allowing the solution to be re-used for reprocessing temperature-sensitive (and other) instruments if the glutaraldehyde concentration is found to be greater than 1.8%.

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are all single use indicators used to monitor glutaraldehyde concentration in specific solutions. The differences between the proposed Browne Aldahol Glutaraldehyde Indicator and predicate device are limited to differences in the device design and materials. These differences do not raise any new issues of safety and efficacy.

A summary of the technological characteristics of the new device in comparison to those of the predicate device is provided in Section 12 of this premarket notification.

The following table summarizes the verification activities that were performed, with their respective acceptance criteria and results, to demonstrate that the Browne Aldahol Glutaraldehyde Indicator is safe and effective. These studies confirm that .the device's performance meets the requirements of its pre-defined acceptance criteria and intended uses.

Test of 6 Lots	Acceptance Criteria		Study Result
	FAIL @ 1.8%	PASS @ 2.3%	
Performance Testing	100%	≥ 80%	**Pass**
Blind Study Testing	100%	≥ 80%	**Pass**
Simulated Use (Contaminants) Testing	100%	≥ 80%	**Pass**
Test Strip Life Outside the Bottle	100%	≥ 80%	**Pass**
Aggressive Chemical Stability Testing	100%	≥ 80%	**Pass**
Specificity Testing for glutaraldehyde	100% FAIL for Tap Water		**Pass**
Stability Testing in three storage environments	100%	≥ 80%	**Pass**
In-Use Stability Testing in three storage environments	100%	≥ 80%	**Pass**

The Browne Aldahol Glutaraldehyde Indicator is substantially equivalent to its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Bill Brodbeck
Senior Manager, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

JUN - 4 2012

Re: K120435
Trade/Device Name: Browne Aldahol Glutaraldehyde Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: May 10, 2012
Received: May 11, 2012

Dear Dr. Brodbeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

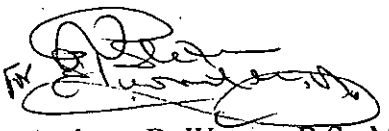
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120435

Device Name: Browne Aldahol Glutaraldehyde Indicator

Indications for Use:

The Browne Aldahol Glutaraldehyde Indicator is a glutaraldehyde concentration monitor dedicated for use with Aldahol V High-Level Disinfectant. The purpose of the Browne Aldahol Glutaraldehyde Indicator is to monitor glutaraldehyde concentration greater than 1.8%.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie - Wilkins
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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